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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/964,894		09/28/2001	Toru Takehisa	011307	07 1326	
23850	7590	04/19/2004		EXAMINER		
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP				MACHUGA, JOSEPH S		
1725 K STR	EET, NW	•				
SUITE 1000	•			ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20006				3762	/i	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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7	Application No.	Applicant(s)	And
Office Antion Comment	09/964,894	TAKEHISA ET AL.	
Office Action Summary	Examiner	Art Unit	
	Joseph S. Machuga	3762	
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet w	ith the correspondence addres	is
A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATI - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicati - If the period for reply specified above is less than thirty (30) days - If NO period for reply is specified above, the maximum statutory - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	ION. FR 1.136(a). In no event, however, may a on. , a reply within the statutory minimum of thi period will apply and will expire SIX (6) MOI statute, cause the application to become A	reply be timely filed rty (30) days will be considered timely. NTHS from the mailing date of this commu BANDONED (35 U.S.C. § 133).	ınication.
Status			
 1) ☐ Responsive to communication(s) filed on 2a) ☒ This action is FINAL. 2b) ☐ 3) ☐ Since this application is in condition for all 	This action is non-final.	rters, prosecution as to the me	erits is
closed in accordance with the practice un	nder <i>Ex parte Quayle</i> , 1935 C.	D. 11, 453 O.G. 213.	
Disposition of Claims			
4) Claim(s) 4-7 is/are pending in the applica 4a) Of the above claim(s) is/are wit 5) Claim(s) is/are allowed. 6) Claim(s) 4-7 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction is	thdrawn from consideration.		
Application Papers			
9) The specification is objected to by the Exact 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection of Replacement drawing sheet(s) including the control of the oath or declaration is objected to by the specific sheet is a specific sheet of the specific sheet in the specific sheet is a specific sheet in the spec	☐ accepted or b)☐ objected to to the drawing(s) be held in abeya correction is required if the drawing	ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of: 1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International E * See the attached detailed Office action for	uments have been received. uments have been received in the e priority documents have been Bureau (PCT Rule 17.2(a)).	Application No n received in this National Sta	ge
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-94) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/5) Paper No(s)/Mail Date	18) Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application (PTO-152 	2)

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Response to Arguments

1. Applicant's arguments filed January 22, 2004 have been fully considered but they are not persuasive. Applicant argues that the Anazawa reference teaches that composite membranes obtained by coating or clogging are undesirable. While it is noted in the reference that it's difficult to manufacture, it is not undesirable. The reference notes in column 2 that this material has an extremely high gas permeability rate and a higher gas exchange rate than the homogeneous membrane. These features are enormously useful in artificial lungs because the thickness can be correspondingly reduced. So there is motivation to look to compositions such as that taught by Kashiwabara and Motomura.

Further, while it is true Motomura does not disclose the material claimed it does teach that dimethyl ditetradecyl ammonium salt and dimethyl dioctadecyl ammonium salt are cationic compound having similar properties and produce similar results when dissolved with heparin (note claim 3 and the example on page 5.) This teaching would provide the motivation to modify Kashiwabara's material to make obvious the coating material recited in the claims.

Finally, to use this material in Anazawa's device is considered obvious given the teachings provided for in that reference as discussed above.

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For these reasons the claimed invention is considered taught by the prior art.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al (#5192320) in view of Kashiwabara et al (EP-1057492) and Motomura et al (EP-0769503.)

Anazawa et al disclose an artificial lung. The reference teaches (note column 6 lines 22-52) that the membrane of the device should be made of poly(4-methylpentene-1.) The O₂ and ethanol permeation rates disclosed in the reference are within the limits defined in the claims. Not disclosed by this document is the surface coating that is derived from heparin and a quaternary aliphatic alkyl ammonium salt.

Kashiwabara et al disclose a blood compatible composition for use as a coating material in medical devices such as a pump-oxygenator, artificial heart, etc. The essential material in the composition is an organic cationic compound and heparin or heparin

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derivative. The reference teaches (note paragraph 22) that in addition to an organic cationic compound having between 24-32 carbon atoms the compound can include an organic cationic compound having 4 alkyl groups and more than 32 carbon atoms. In Example 3, dimethyl didodecyl ammonium chloride and dimethyl ditetradecyl ammonium chloride were mixed in the proportions claimed. Thereafter heparin was dissolved in the mixture. The resulting product was a coating material having anti-thrombogenic properties.

Motomura et al teach that dimethyl ditetradecyl ammonium salt and dimethyl dioctadecyl ammonium salt are cationic compound having similar properties and produce similar results when dissolved with heparin (note claim 3 and the example on page 5.)

Given these disclosures, it would have been obvious to one of ordinary skill in the art to add Kashiwabara et al's coating to the blood contacting side of the membrane in Anazawa et al's device for the purpose of impart anti-thrombogenic properties thereto. To use dimethyl dioctadecyl ammonium salt in place of dimethyl ditetradecyl ammonium salt in Kashiwabara et al's product and process (noted above) would also have been obvious to one of ordinary skill in the art given Motomura et al's teaching that they are known equivalents for this purpose and would result in predictable variations in the lifetime of the coating, capability of the coating, etc.

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Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph S. Machuga

Examiner Art Unit 3762

ANGELA D. SYKES SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

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